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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,937	04/08/2004	Lisa Lynn Shafer	P-21023.00US	9727

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,937	SHAFER, LISA LYNN	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on November 30, 2005. Claims 1-69 are active.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13, 19-21, 23-24, 27-31, 34-35, 40, 42, 47, 55, 57 and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rezai (U.S. 2002/0116030). As to Claims 1-2 and 5, Rezai discloses a method comprising stimulating a sympathetic neuron of a mammalian subject in an amount effective to inhibit the release of a proinflammatory mediator (see Rezai Abstract, page 1, paragraphs 4-7 and page 2, paragraphs 14 and 19). The Examiner takes the position that the oscillating electrical signal comprising a plurality of electrical pulses of the Rezai method, operated at a frequency range between about 2 Hz and 2500 Hz, having a voltage between about 0.1 μV to about 20V and a pulse width between 10 microseconds to about 1,000 microseconds is synonymous with an "amount effective to inhibit the release of a proinflammatory mediator" due to Applicant's disclosure pages 17 and 26-28 (see Rezai page 2, paragraph 19 and page 5, paragraph 38). The Examiner also notes that although the method of Rezai is not explicitly disclosed "to inhibit the release of a proinflammatory mediator", the oscillating electrical signal comprising a plurality of electrical pulses of the Rezai method is capable of inhibiting the release of a proinflammatory mediator and "[t]he discovery of a previously unappreciated property of a

prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of an unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ430, 433 (CCPA 1977) (MPEP § 2112).

4. As to Claims 3-4, Rezai discloses that the electrode 122, used to stimulate the sympathetic neuron of interest, is coupled to a pulse generator, which may be implanted on or adjacent to the electrode 122 (see Rezai page 4, paragraph 37).

5. As to Claims 6-8, Rezai discloses that the electrode 122 may be used to electrically stimulate any cervical ganglion or ganglia, thoracic ganglion or ganglia, lumbar ganglion or ganglia or sacral ganglia or any combination thereof associated with a particular physiological disorder to be affected, modulated, treated, alleviated or ameliorated (see Rezai page 1, paragraph 5). The Examiner takes the position that these "ganglion or ganglia" disclosed by Rezai comprise neurons of the splenic nerve and makes reference to Applicant's disclosure pages 17-18.

6. As to Claims 9-10, Rezai discloses that the stimulation comprises an oscillating electrical signal, comprising a plurality of electrical pulses, operated at a frequency range between about 2 Hz and 2500 Hz, having a voltage between about 0.1 μV to about 20V and a pulse width between 10 microseconds to about 1,000 microseconds (see Rezai page 2, paragraph 19 and page 5, paragraph 38).

7. As to Claims 11-12, Rezai discloses that the electrode 122, used to stimulate the sympathetic neuron of interest, is coupled to a pulse generator, which may be implanted on or adjacent to the electrode 122 (see Rezai page 4, paragraph 37).

8. As to Claim 13, Rezai discloses that the plurality of electrical pulses are applied to the neuron (see Rezai page 1, paragraphs 2, 4-5 and 9).

9. As to Claims 19-21, Rezai discloses that the cell is a sympathetic neuron in a patient suffering from, or at risk for, a disease or disorder such as asthma, pancreatitis, inflammatory bowel disease, congestive heart failure, spinal cord injury, arterioscelerosis, and a plurality of others others. It is inherent that these diseases or disorders are mediated by an inflammatory cytokine cascade and the Examiner makes reference to Applicant's disclosure pages 8-12 (see Rezai page 1, paragraphs 9-10, page 2, paragraphs 10-11, page 3, paragraphs 26-30, page 5, paragraphs 44-45, page 6, paragrapsh 46-48 and 50, page 7, paragraphs 50-56 and page 8, paragraphs 59-69).

10. As to Claim 23, Rezai discloses that the method is capable of effecting a variety of physiological disorders or pathological conditions by placing an electrode 122 adjacent to or in communication with at least one ganglion along the sympathetic nerve chain and stimulating the at least one ganglion until the physiological disorder or pathological condition has been effected (see Rezai Abstract, page 1, paragraphs 4-5 and page 4, paragraph 36).

11. As to Claim 24, Rezai discloses that postganglionic sympathetic nerve fibers converge, in small nodes of nerve cells, called ganglia (see Rezai page 3, paragraph 28) and further discloses that the method may comprise stimulation any cervical ganglia, thoracic ganglia, lumbar ganglia or sacral ganglia or combination thereof (see Rezai page 1, paragraph 5).

12. As to Claims 27, 34-35, 40, 42, 47, 55, 57 and 59-60, Rezai discloses a method comprising stimulating a sympathetic neuron in a patient in an amount sufficient to inhibit the inflammatory cytokine cascade (see Rezai Abstract, page 1, paragraphs 4-7 and page 2, paragraphs 14 and 19). The Examiner takes the position that the oscillating electrical signal, comprising a plurality of electrical pulses of the Rezai method operated at a frequency range between about 2 Hz and 2500 Hz, having a voltage between about 0.1 μV to about 20V and a pulse width between 10 microseconds to about 1,000 microseconds is synonymous with an "amount sufficient to inhibit the inflammatory cytokine cascade" due to Applicant's disclosure pages 17 and 26-28 (see Rezai page 2, paragraph 19 and page 5, paragraph 38). The Examiner also notes that although the method of Rezai is not explicitly disclosed "to inhibit the inflammatory cytokine cascade", the oscillating electrical signal comprising a plurality of electrical pulses of the Rezai method is capable of inhibiting the inflammatory cytokine cascade and "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of an unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ430, 433 (CCPA 1977) (MPEP § 2112).

Rezai also discloses that the cell is a sympathetic neuron in a patient suffering from, or at risk for, a disease or disorder such as asthma, pancreatitis, inflammatory bowel disease, congestive heart failure, spinal cord injury, arteriosclerosis, and a plurality of others others. It is inherent that these diseases or disorders are mediated by an inflammatory cytokine cascade and

the Examiner makes reference to Applicant's disclosure pages 8-12 (see Rezai page 1, paragraphs 9-10, page 2, paragraphs 10-11, page 3, paragraphs 26-30, page 5, paragraphs 44-45, page 6, paragrapsh 46-48 and 50, page 7, paragraphs 50-56 and page 8, paragraphs 59-69).

13. As to Claim 28, Rezai discloses that an electrode 122, coupled to a pulse generator is used to stimulate the sympathetic neuron of interest (see Rezai page 4, paragraph 37).

14. As to Claim 29, Rezai discloses that the method is capable of effecting a variety of physiological disorders or pathological conditions by placing an electrode 122 adjacent to or in communication with at least one ganglion along the sympathetic nerve chain and stimulating the at least one ganglion until the physiological disorder or pathological condition has been effected (see Rezai Abstract, page 1, paragraphs 4-5 and page 4, paragraph 36).

15. As to Claim 30, Rezai discloses that postganglionic sympathetic nerve fibers converge, in small nodes of nerve cells, called ganglia (see Rezai page 3, paragraph 28) and further discloses that the method may comprise stimulation any cervical ganglia, thoracic ganglia, lumbar ganglia or sacral ganglia or combination thereof (see Rezai page 1, paragraph 5).

16. As to Claim 31, Rezai discloses that the electrode 122 may be used to electrically stimulate any cervical ganglion or ganglia, thoracic ganglion or ganglia, lumbar ganglion or ganglia or sacral ganglia or any combination thereof associated with a particular physiological disorder to be affected, modulated, treated, alleviated or ameliorated (see Rezai page 1, paragraph 5). The Examiner takes the position that these "ganglion or ganglia" disclosed by Rezai comprise neurons of the splenic nerve and makes reference to Applicant's disclosure pages 17-18.

17. Claims 1, 14-16 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Straub et al. (*Neuronal Regulation of Interleukin 6 Secretion in Murine Spleen: Adrenergic and Opioidergic Control*) (herein Straub). Straub discloses a method for inhibiting the release of a proinflammatory mediator from splenic cells comprising stimulating a spleen slice of a mammalian subject (i.e. mice) in an amount effective to inhibit the release of the proinflammatory cytokine, Interleukin 6 (IL-6) (see Straub page 1634). The Examiner takes the position that a slice of the spleen comprises sympathetic neurons throughout its mass, including those of the splenic nerve, and direct stimulation of that spleen slice via electrodes as disclosed by Straub results in stimulation of at least one sympathetic neuron and of the entire spleen slice itself (see Straub Abstract and pages 1633-1639).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 14, 17-18, 22-26, 33, 36-39, 41, 43-46, 48-54, 56, 58 and 61-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Tracey. As to Claims 14 and 17, Rezai discloses the claimed invention as discussed above except that the inhibition of a profinflammatory mediator is not specified to be inhibition of an inflammatory cytokine called TNF-α.

Tracey, however, teaches that inflammation and other deleterious conditions (such as septic shock caused by endotoxin exposure) are often induced by proinflammatory cytokines

such as tumer necrosis factor (TNF-α) (see Tracey column 1, lines 28-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Rezai to comprise inhibition of the inflammatory cytokine TNF-α in order to include treatment of sepsis in the list of physiological disorders capable of being affected, modulated, treated, alleviated or ameliorated by the invention.

20. As to Claim 18, Rezai discloses the claimed invention as discussed above except that the proinflammatory mediator is not specified to be a chemokine.

Tracey, however, teaches a method of stimulating a nerve to inhibit the release of a pro-inflammatory cytokine such as IL-8. IL-8 is produced in acute and chronic inflammation to mobilize and activate white blood cells so it is inherent that inhibition of IL-8 inhibits the mobilization and activation of white blood cells during acute and chronic inflammation.). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Rezai to comprise inhibition of the inflammatory chemokine such as IL-8 in order to stop the mobilization and/or activation of white blood cells during acute and chronic inflammatory responses in a patient.

21. As to Claim 22, 26, 33, 36-39, 41, 43-46, 48-54, 56, 58 and 61-69, Rezai discloses the claimed invention as discussed above except that the method does not further comprise stimulating a vagus nerve for treatment of diseases or disorders that are mediated by an inflammatory cytokine cascade such as endotoxic shock, appendicitis, peptic, gastric and duodenal ulcers, peritonitis, hepatitis, allergy, anaphylactic shock, organ ischemia, reperfusion injury, sepsis, septicemia, cachexia, septic abortion, disseminated bacteremia, burns, coeliac disease, adult respiratory distress syndrome, Rheumatoid arthritis, allograft rejection, graft-

versus-host disease, multiple sclerosis, Crohn's disease, acute ulcerative colitis, chronic ulcerative colitis, nosicomial infection, Alzheimer's disease and coeliac disease. .

Tracey, however, discloses a method for inhibiting the release of a pro-inflammatory cytokine from a mammalian cell comprising stimulating a neuron (i.e. the vagus nerve) of a mammalian subject in an amount effective to inhibit the release of the pro-inflammatory cytokine (see Tracey column 10, lines 17-56) to treat a wide variety of diseases or disorders that are mediated by an inflammatory cytokine cascade such as endotoxic shock, appendicitis, peptic, gastric and duodenal ulcers, peritonitis, hepatitis, allergy, anaphylactic shock, organ ischemia, reperfusion injury, sepsis, septicemia, cachexia, septic abortion, disseminated bacteremia, burns, coeliac disease, adult respiratory distress syndrome, Rheumatoid arthritis, allograft rejection, graft-versus-host disease, multiple sclerosis, Crohn's disease, acute ulcerative colitis, chronic ulcerative colitis, nosicomial infection, Alzheimer's disease and coeliac disease (see Tracey column 1, lines 20-67, column 2, lines 1-34, column 3, lines 7-67, column 4, lines 1-67 and column 5, lines 1-16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Rezai to include stimulation of a vagus never to inhibit release of a proinflammatory mediator for treatment of any one of the following: endotoxic shock, appendicitis, peptic, gastric and duodenal ulcers, peritonitis, hepatitis, allergy, anaphylactic shock, organ ischemia, reperfusion injury, sepsis, septicemia, cachexia, septic abortion, disseminated bacteremia, burns, coeliac disease, adult respiratory distress syndrome, Rheumatoid arthritis, allograft rejection, graft-versus-host disease, multiple sclerosis, Crohn's disease, acute ulcerative colitis, chronic ulcerative colitis, nosicomial infection, Alzheimer's disease and coeliac disease, as taught by Tracey to better the invention.

22. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai. Rezai discloses the claimed invention as discussed above except that the method does not further comprise direct stimulation of a peripheral tissue or organ served by the splenic nerve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Rezai with direct stimulation of a peripheral tissue or organ served by the splenic nerve, because Applicant has not disclosed that such stimulation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the sympathetic nerve stimulation as taught by Rezai, because it stimulation in an amount effective to inhibit the release of a proinflammatory mediator and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Rezai.

Therefore, it would have been an obvious matter of design choice to modify Rezai to obtain the invention as specified in the claim(s).

Double Patenting

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-129 of copending Application No. 10/820,677. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are a broadening of the scope of the claims presented in Application No. 10/820,677 or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

25. Applicant's arguments with respect to claims 1-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 01/19/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766